



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: John Kevin COLLINS et al

Serial No.:

10/783020

Group Art Unit: 1651

Filed:

February 23, 2004

For:

BIFIDOBACTERIUM IN THE TREATMENT

OF INFLAMMATORY DISEASE

THIRD INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

As a means of complying with the duty of disclosure under 37 CFR §1.56, and in accordance with 37 CFR §§1.97 and 1.98, Applicant(s), through the undersigned attorney, submits this Information Disclosure Statement. The patents, publications or other information submitted herewith are listed on the attached Form PTO-1449 and copies are attached.

In accordance with 37 CFR §1.97(b)(3), this Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits of the aboveidentified application.

Copies of all references can be found in the copending application Serial No.



Respectfully submitted,

JACOBSON HOLMAN PLLC

By: ____

John C. Holman

Registration No. 22,769

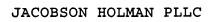
400 Seventh Street, N.W. Washington, DC 20004 (202) 638-6666

Atty. Dkt. No.: P66879US3

Date: July 27, 2004

10/376602.

FORM PTO-1449 (Modified)



400 SEVENTH STREET, N.W.

WASHINGTON, D.C. 20004-2201

ATTY. D	OCKET	'NO.: <u>P668</u>	79US3	GROUP ART U	NIT:	165	1	
SERIAL	NO.:	<u> 10/7</u>	83020	FILING DATE	: <u>F</u> e	bruary	23, 2	2004
APPLICA	NT(S)	: <u>COLL</u>	INS	TODAY'S DAT	Έ: <u>Ju</u>	ily 27,	2004	
*****	****	*****	*****	*****	*****	*****	****	****
			U.S. PA	ATENT DOCUMENTS				
*EXAMINER		DOCUMENT				SUB-	FILIN	G DATE
INITIAL		<u>NUMBER</u>	DATE	NAME	<u>CLASS</u>	<u>CLASS</u>	If Appr	opriate)
	AA	4435389	03/06/84	<u>Mutai et al</u>	424	<u> 181</u>		
	AB	5032399	<u>07/16/91</u>	<u>Gorbach et al</u>	424	<u>93</u>		
	AC	<u>5443826</u>	<u>08/22/95</u>	Borody	424	93		
	AD	<u>5922375</u>	<u>07/13/99</u>	Luchansky et al	426	<u>61</u>		
	ΑE	6132710	10/17/00	<u>Panigraphi et al</u>	424_	<u>93</u>		
	AF	6645530	11/11/03	Borody	424	<u>543</u>		
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			FOREIGN	PATENT DOCUMENTS				
		DOCUMENT				SUB-	TRANS	LATION
		NUMBER_	DATE	COUNTRY	<u>CLASS</u>	<u>CLASS</u>	YES)	(NO)
 	AG	0384319B1	08/29/90	<u>Europe</u>				
	AH	0508701B1	10/14/92	<u>Europe</u>				
	ΑI	<u>0904784A1</u>	03/31/99	Europe				
	AJ	<u>1312667A1 </u>	<u>05/21/03</u>	Europe		 		ļ
	AK	1503094	<u>03/08/78</u>	<u>Great Britain</u>				
	AL	2091075	<u>09/27/97</u>	<u>Russia</u>			Abst	<u>ract</u>
	AM	2109054	04/20/98	<u>Russia</u>			Abst:	ract
	AN	<u>WO89/05849</u>	<u>06/29/89</u>	WIPO				
	AO	WO90/01335	02/22/90	WIPO				
	AP	<u> WO90/09398</u>	<u>08/23/90</u>	WIPO				
	AQ	WO97/35596	10/02/97	WIPO				
	AR	WO98/00035	<u>01/08/98</u>	WIPO		····		
	AS	WO99/51631	10/14/99	WIPO				
 	AT	<u>WO99/62348</u>	12/09/99	WIPO				
	AU	WO01/37865	05/31/01	WIPO				
	AV	9-241173	09/16/97	<u>Japan</u>			Abst	ract
EXAMINER				DATE CONSIDERED				

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****	*****	*******	*****	******		
	OTHER	ART (Including Author, Ti	tle, Date, Pertinent	Pages, Etc.)		
	AW	Kühn et al, CELL, Vol 75, 10/22/93, pgs. 263-274,				
		Interleukin-10-Deficient	Mice Develop Chroni	<u>c Enterocolitis</u>		
	AX	Marteau et al, FEMS MICRO	DBIOLOGY REVS 12, 19	93, pgs. 207-220,		
		Potential of using laction	c acid bacteria for	therapy and		
	AY	Rumney et al, CARCINOGENE	ESIS, Vol 14, No 1,	1993, pgs. 79-84,		
		Effects of risk-associate	ed human dietary mac	rocomponents on		
	AZ	O'Sullivan et al, IRISH d	JOUR OF MED SCI, PRO	C OF THE IRISH SOC		
		OF GASTROENTEROLOGY, Dec	4-5, 192, Probiotic	Bacteria in the		
	AA1	Adachi, THE LACTIC ACID E	BACTERIA, Vol 1, 199	2, pgs. 233-261,		
		Lactic Acid Bacteria and	the Control of Tumo	urs		
	AB1	Chauviere et al, JOURNAL	OF GENERAL MICROBIO	LOGY 138, 1992, pgs.		
		1689-1696, Adhesion of hu	ıman <i>Lactobacillus</i> a	acidophilus strain		
	AC1	O'Sullivan et al, TRENDS	IN FOOD SCIENCE & T	ECH, Vol 31, Dec.		
		1992, pgs. 309-314, Probi	otic bacteria: myth	or reality		
	AD1	Tancrede, EUR J CLIN MICE	ROBIOL INFECT DIS, V	ol 11, No 11, Nov.		
		1992, pgs. 1012-1015, Rol	<u>le of Human Microflo</u>	ra in Health and		
	AE1	Vaughan et al, JOUR OF AI	PPL BACTERIOLOGY 73,	1992, pqs. 299-308,		
		Identification and charac	cterization of helve	ticin V-1829, a		
	AF1	Malefyt et al, J EXP MED,				
		Interleukin 10 (IL-10) ar	nd Viral IL-10 Stron	gly Reduce		
	AG1	O'Sullivan et al, IRISH S				
		Jun 7-8, 1991, pgs. 419-4				
	AH1	Mangan et al, JOUR OF IMM				
		Mar 1, 1991, Lipopolysaco				
	AI1	Toba et al, LTRS IN APPL				
		Potential of Lactobacilly				
	AJ1	Wahl et al, JOUR OF IMMUN	· · · · ·			
		1, 1991, IFN-y Inhibits	•			
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EXAMINER			DATE CONSIDERED			
						

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	OTHER	ART (Including Author,	Title, Date, Pertinent Pages, E	Etc.)		
	AK1	Cicco et al, BLOOD, Vo	l 75, No 10, 1990, pgs. 2049-20	52,		
		Inducible Production of Interleukin-6 by Human				
	AL1	Donnelly et al, JOUR O	F IMMUNOLOGY, Vol 145, No 2, Ju	<u>l 15, 1990, </u>		
		pgs. 569-575, Differen	<u>tial Regulation of IL-1 Product</u>	ion in		
	AM1	Gatanaga et al, PROC N	ATL ACAD SCI, Vol 87, pgs. 8781	<u>-8784, Nov.</u>		
		1990, Purification and	characterization of an inhibit	or		
	AN1	Gilliland, FEMS MICROB	<u> IOLOY REV 87, pgs. 175-188, 199</u>	<u>0, Health</u>		
		and nutritional benefi	ts from lactic acid bacteria			
	A01	Fuller, JOUR OF APPL B	ACTERIOLOGY 66, 1989, pgs. 365-	378,		
		Probiotics in man and	animals			
	AP1	Dinarello et al, REV O	F INFECTIOUS DIS, Vol 10, No 1,	Jan/Feb		
		1988, pgs. 168-189, Ne	w Concepts on the Pathogenesis	of Fever		
	AQ1	Ferrante et al, INT AR	<u>CHS ALLERGY APPL IMMUN 86, 1988</u>	, pgs. 82-		
		91, Effects of Tumour	Necrosis Factor Alpha and Inter	<u>leukin-1</u>		
	AR1	Kim, CULTURED DAIRY PR	OD JOUR, Aug 1988, pgs. 6-9, Ch	aracter-		
		ization of Lactobacill	<u>i and Bifidobacteria as applied</u>	to		
	AS1	Shanahan et al, INFLAM	MATORY BOWEL DISEASEINTL CON	GRESS, 1988		
		pgs. 101-106, In vivo	primed cytotoxic T cells in inf	lammatory		
	AT1	Bachwich et al, BIOCHE	M AND BIOPHYS RES COMMUN, Vol 1	36, No 1,		
		Apr 14, 1986, pgs. 94-	101, Tumor Necrosis Factor Stim	ulates		
	AU1	Wong et al, NATURE, Vo	l 323, Oct 1986, pgs. 816-819,	<u>Antiviral</u>		
		effects of recombinant	tumour necrosis factor in vita	ro		
	AV1	Anand et al, CULT DAIR	Y PROD 2, 1985, pgs. 21 and 23,	Anti-		
			<u>ociated with <i>Bifidobacterium b</i>i</u>			
	AW1	Kawakami et al, JOUR C	F IMMUNOLOGY, Vol 132, No 5, Ma	y 1984, A		
		Group of Bactericidal	<u>Factors Conserved by Vertebrate</u>	s for		
	AX1		NAL MICROFLORA IN HEALTH & DISE			
		pgs. 517-539, Effect o	f Dietary and Environmental Str	ess on		
			DATE GOVERNORD			
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OTHER	ART (Including Author, Tit	le, Date, Pertinent Pages, Etc.)
AY1	Savage, IN: MICROBIAL ECO	LOGY OF THE GUT, 1977, pgs. 277-310,
	Interaction between the h	ost and its microbes
AZ1	Crabbe et al, INT ARCH AL	LERGY 34, 1968, pgs. 362-375, The
	Normal Microbial Flora as	a Major Stimulus for Proliferation
AA2	O'Mahony et al, PROC OF B	RITISH NUTRITIONAL FOUNDATION, 2000,
	pgs. 63-70, Probiotic Bac	teria and the Human Immune System
AB2	McBrearty et al, PROC OF	BRITISH NUTRITIONAL FOUNDATION, 2000,
	pgs. 97-107, Probiotic Bi	fidobacteria and Their Identification
AC2	Blum et al, TRENDS IN FOO	D SCI & TECH 10, 1999, pgs. 405-410,
	Adhesion studies for prob	iotics: need for validation and
AD2	Collins et al, GASTROENTE	ROLOGY, Vol 116, No 4, Apr 1999, 1 pg.
	A Controlled Trial of Pro	<u>biotic Treatment of IL-10 Knockout Mice</u>
AE2	Collins et al, GASTROENTE	ROLOGY, Vol 116, No 4, Apr 1999, 1 pg.
	Probiotics and Man - The	Host Microbe Interface
AF2	Darveau, NATURE BIOTECHNO	LOGY, Vol 17, Jan 1999, pg. 19,
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AG2	Dunne et al, GASTROENTERO	LOGY, Vol 116, No 4, Apr 1999, 2 pgs.
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AH2	O'Mahony et al, IR J MED	SCI, Vol 168, No 5, 1999, Consumption
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AI2	O'Mahony et al, SIXTH SYM	P ON LACTIC ACID BACTERIA, Sept 19/
	23, 1999, 2 pgs., Probiot	ic Treatment of Enterocolitis in
AJ2	Gardiner et al, SIXTH SYM	P ON LACTIC ACID BACTERIA, Sept 19/
	23, 1999, 2 pgs., Cheddar	Cheese as a Probiotic Delivery System
AK2	Gardiner et al, SIXTH SYM	P ON LACTIC ACID BACERTIA, Sept 19/
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AL2	O'Mahony et al, IRISH JOU	R OF MED SCI, Nov 26/27, 1999, UCC118
	Modulates Proinflammatory	Cytokine Production in Vitro
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OTHER 2	ART (Including Author, T	itle, Date, Pertinent Pages, Etc.)			
AM2	Gardiner et al, J DAIRY	SCI Vol 82, No 7, 1999, pgs. 1379-1387,			
	Evaluation of Cheddar Cheese as a Food Carrier for Delivery				
AN2	Gardiner et al, J AGRIC	FOOD CHEM, Vol 47, 1999, pgs. 4907-4916,			
	Influence of a Probiotic	Adjunct Culture of Enterococcus			
AO2	Mattila-Sandholm et al,	TRENDS IN FOOD SCI & TECH, Vol 10, 1999,			
	pgs. 393-399, Probiotics	: towards demonstrating efficacy			
AP2	McCracken et al, PROBIOT	CICS A CRITICAL REVIEW, 1999, pgs. 85-113			
	Probiotics and the Immur	e System			
AQ2	Murphy et al, GASTROENTE	ROLOGY, Vol 116, No 4, 1999, 2 pgs.,			
	Evaluation and Character	isation of Probiotic Therapy in the			
AR2	Murphy et al, MICROBIAL	ECOLOGY IN HEALTH & DISEASE, 1999, pgs.			
	<u>149-157</u> , <i>In vivo</i> assessm	ment of potential probiotic			
AS2	Present et al, NEW ENGLA	ND JOUR OF MED, Vol 340, No 18, May 6,			
	1999, pgs. 1398-1405, In	fliximab for the Treatment of			
AT2	Reddy, AMER SOC FOR NUTR	SCI, 1999, pgs. 1478S-1482S, Possible			
	Mechanisms by Which Pro-	and Prebiotics Influence Colon			
AU2	O'Halloran et al, INTL D	AIRY JOUR, Vol 8, No 5/6, 1998, 3 pgs.,			
	Adhesion of Potential Pr	obiotic Bacteria to Human Epithelial			
AV2	Flynn et al, INTL DAIRY	JOUR, Vol 8, No 5/6, 1998, 3 pgs.,			
	Isolation and Characteri	sation of the Novel Antibacterial			
AW2	Charteris et al, JOUR OF	FOOD PROTECTION, Vol 61, No 12, 1998,			
	pgs. 1636-1643, Antibiot	ic Susceptibility of Potentially			
AX2	Charteris et al, Jour of	APPL MICROBIOLOGY, Vol 84, 1998, pgs.			
	759-768, Development and	application of an in vitro			
AY2	Collins et al, INT DAIRY	JOUR 8, 1998, pgs. 487-490, Selection			
	of Probiotic Strains for	Human Applications			
AZ2	Gardiner et al, APPL AND	ENVIR MICROBIOLOGY, Vol 64, No 6, 1998,			
pgs. 2192-2199, Development of a Probiotic Che		ent of a Probiotic Cheddar Cheese			
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	OTHER	ART (Including Author, Title, Date, Pertinent Pages, Etc.)
	AA3	Gardiner et al, INTL DAIRY JOUR, Vol 8, No 5/6, 1998, 3 pgs.,
		Characterisation of Cheddar Cheese Harboring Probiotic
	AB3	Kato et al, LIFE SCIENCES, Vol 63, No 8, 1998, pgs. 635-644,
		Suppressive Effects of the Oral Administration of
	AC3	Morrisey et al, IR JOUR OF MED SCI, Vol 167, Supp No 8, 1998,
		2 pgs., Election of a Probiotic Strain to Modify
	AD3	Murphy et al, INTL DAIRY JOUR, Vol 8, No 5/6, 1998, Long-term
		Colonisation with Lactobacillus salivarius subsp. salivarius
	AE3	Feency et al, INTL DAIRY JOUR, Vol 8, No 5/6, 1998, Lack of
		Specific Systemic Immune Response on Oral Consumption of
	AF3	O'Riordan et al, INTL DAIRY JOUR, Vol 8, No 5/6, 1998, Asess-
		ment of Bifidobacterium Strains for antimicrobial and
	AG3	Collins, FUNCTIONAL FOOD RESEARCH IN EUROPE, Oct 1/2, 1998, pg.
		124, Probiotics and Inflammatory Bowel Disease: Animal Models
	AH3	Collins et al, FUNCTIONAL FOOD RESEARCH IN EUROPE, Oct 1/2, 1998
		pgs. 40-41, Demonstration of Probiotic Function in a Double
	AI3	O'Riordan et al, JOUR OF APPL MICROBIOLOGY, Vol 85, 1998, pgs.
		103-114, Evaluation of bifidobacteria for the production of
	AJ3	Panwala et al, JOUR OF IMMUNOLOGY, Vol 161, 1998, pgs. 5733-
		5744, A Novel Model of Inflammatory Bowel Disease: Mice
	AK3	Raychaudhuri et al, NAT BIOTECHNOL, Vol 16, 1998, pgs. 1025-1031
		Fully mobilizing host defense: Building better vaccines
	AL3	Salminen et al, INTL JOUR OF FOOD MICROBIOLOGY 44, 1998, pgs.
		93-106, Demonstration of safety of probiotics - a review
	AM3	Cong et al, GASTROENTEROLOGY 115, 1998, pgs. 1595-1600, Genes,
		Bacteria, and T Cells: Ingredients for Inflammatory Bowel
	AN3	Stallmach et al, TRENDS IMMUNOLOGY TODAY, Vol 19, No 10, Oct.
		1998, pgs. 438-441, Induction and modulation of
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		•				
	AO3	Stant	Stanton et al, INT DAIRY JOUR 8, 1998, pqs. 491-496, Probiotic			
		Chees				
	AP3			INIC BIOCHEM & MED TEST, Vol 19(5),		
			- · · · · · · · · · · · · · · · · · · ·	opotentiating Activity of		
	AQ3			NTEROLOGY INTL, Vol. 11, Supp 1, 1998,		
	~			in the IBD Pathogenesis - Possible		
	AR3			AND IMMUNITY, Jul 1998, pqs. 3183-318		
		Mucosal Delivery of Murine Interleukin-2 (IL-2) and IL-6 by				
	AS3	,		R SEMIN IMMUNOPATHOL 18, 1997, pgs. 55		
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	AT3			R OF FOOD MICROBIOLOGY 35, 1997, pqs.		
,		-		enumeration and identification of		
	AU3			OCYTE BIOLOGY, Vol 62, Dec 1997, pgs.		
				e to <i>Listeria monocytogenes</i> in tumor		
	AV3			MICROBIOL 51, 1997, pgs. 341-373,		
		Transcriptional Control of the Pseudomonas Tol Plasmid				
	EWA	•	_	EVIEWS IN IMMUNOLOGY 17, 1997, pqs. 54		
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	AX3		-	ECH TODAY 11(4), 1997, pqs. 230-233,		
			oping Fields in Food			
	AY3			3, 1997, pqs. 73-78, Pharmaceutical		
				ent of Anaerobic and Other Infections		
	AZ3			ROBIOLOGY LTRS 156, 1997, pgs. 259-264		
				diversity within the genus		
	AA4			OL 68, 1997, pgs. 70-85, The Immuno-		
				-12 in T-Helper Cell Development		
	AB4			EROLOGY 112, 1997, pqs. 1045-1046,		
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	AC4	Mattila-Sandholm, DEMONSTRATI			
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	AD4	Collins, DEMONSTRATION FAIR C		15, 1996, pg. 27,	
		Selection and safety criteria			
	AE4	Arihara et al, LTRS IN APPL M			
		Salivacin 140, a novel bacter			
	AF4	Collins et al, INT CONG & SYM			
		<u>Probiotic bacteria - interact</u>			
	AG4	Daly et al, ANTONIE VAN LEEUW			
		technology of lactic acid bac	_		
	AH4	Neutra et al, ESSENTIALS OF M			
		M Cells as a Pathway for Anti			
	AI4	Collins, BOOK OF ABSTRACTS FR			
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	AK4	Lee et al, TRENDS IN FOOD & T	ECH, Vol 6, Jul	1995, pgs. 241-245,	
		The coming of age of probioti	CS		
	AL4	Medaglini et al, PROC NATL AC			
		-6872, Mucosal and systemic i	_		
	AM4	Sarem-Damerdji et al, FEMS MI	CROBIOLOGY LTS 1	.31, 1995, pgs. 133-	
		137, In vitro colonization ab	ility of human c	colon mucosa by	
	AN4	Shanahan, EXCERPTA MEDICA 13,	1995, pgs. 13-2	28, Pathogenic	
		mechanisms in inflammatory bo	wel disease		
	A04	Thornton et al, GASTROENTEROL			
		1995, Bile tolerance and bile	<u>salt hydrolase</u>	activity of	
	AP4	Brink et al, JOUR OF APPL BAC	TERIOLOGY 77, 19	994, pgs. 140-148,	
		Antimicrobial activity of lac	<u>tobacilll: preli</u>	minary	
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